# Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for MBD Medical's 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the MBD Plate System is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device(s).

**Sponsor:** MBD Medical, LLC
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**Date Prepared:** April 8, 2014

**Proposed Class:** II

**Proprietary Name:** MBD Plate System

**Common Name:** Plate, Fixation, Bone

**Classification Name:** Plate, Fixation, Bone

**Regulation Number:** 21 CFR 888.3030

**Product Codes:** HRS, HWC

**Predicate Device(s):**

| Manufacturer | Device Name | Procode | 510(k) Number | Common Name | Class |
|---|---|---|---|---|---|
| Synthes (USA) | Synthes One-Third Tubular DCL Plate | HRS | K011335 | Plate, Fixation Bone | II |
| Howmedica Osteonics Corp. | Variax Clavicle System | HRS, HWC | K113760 | Plate, Fixation Bone | II |

**Indication for Use**

The MBD Plate System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula.

**Device Description**

The MBD Plate System is a titanium plating system comprised of various length plates and screws. The plates are low profile straight plates ranging in length from 72mm to 136mm. The plate thickness and width are 3mm and 11mm, respectively. Plate sizes are from 6 to 11 holes and each plate hole and/or slot accepts 4.0mm non-locking bone screws. Bone screws range from 12 to 24mm in length. Additionally, the system comprises low-profile 2.5mm diameter fragment screws in lengths from 10 to 24mm.

**Performance Data**

The MBD Plate System has been evaluated through non-clinical performance testing for fatigue and static four-point bend testing. The testing demonstrated that the MBD Plate system components met performance requirements and are as safe and effective as their predicate devices.

**Technological Characteristics and Substantial Equivalence**

The MBD Plate System has the same indications for use, materials, and similar design features as compared with the predicate systems. The bench testing demonstrates that the performance characteristics of the MBD Plate System are equivalent to those of other legally marketed plate/screw systems, and therefore supports a determination of Substantial Equivalence for the proposed indications for use. Any differences between the subject and predicate devices would not render the device NSE, affect the safety or effectiveness, or raise different questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 30, 2014

MBD Medical, LLC
% Jennifer A. Daudelin
Regulatory Consultant III
M Squared Associates, Inc.
575 Eighth Avenue, Suite 1212
New York, New York 10018

Re: K141045
Trade/Device Name: MBD Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: May 9, 2014
Received: May 13, 2014

Dear Ms. Daudelin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Section 4: Indications for Use Statement

**510(k) Number:** K141045

**Device Name:** **MBD Plate System**

**Indications for Use:**

The MBD Plate System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula.

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



Elizabeth D. Frank -S

Division of Orthopedic Devices